



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,856	12/08/2003	Edgar Engleman	03102.0013.NPUS01	3525
27194	7590	11/29/2005	EXAMINER	
HOWREY LLP C/O IP DOCKETING DEPARTMENT 2941 FAIRVIEW PARK DRIVE, SUITE 200 FALLS CHURCH, VA 22042-2924			SCHWADRON, RONALD B	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/730,856

Applicant(s)

ENGLEMAN, EDGAR

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

1. Applicant's election of Group I in the reply filed on 10/28/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 10-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/28/05.
3. Claims 1-9 are under consideration.
4. Applicant needs to delete lines 4-7, page 1 of the specification because said passage indicates that the instant application is filed as a PCT wherein the instant application is actually a continuation of said PCT.
5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the oath filed 4/26/04 indicates on page 1 (because the second b box has an X) that a claim to foreign priority has been made yet no foreign priority document is listed. It is noted that priority to PCT/US02/19023 has already been properly claimed under 35 USC 120, so no claim under 35 USC 119 is *required* or *necessary*. In the event that such a foreign priority claim was made, a certified copy of the PCT would be required.
6. Claim 6 is objected to because of the following informalities. Claim 6, "dos" should be "dose". Appropriate correction is required.
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1644

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Grillo-Lopez (US Patent 6,455,043).

Grillo-Lopez teaches the treatment of Non-Hodgkin's lymphoma with chimeric or humanized monoclonal antibody against CD20 and IFN- $\gamma$  (see abstract, column 3, second and third paragraph, column 4, first paragraph, column 15, last paragraph continued on column 16 and column 2, last paragraph). Grillo-Lopez teaches use of anti CD20 antibody (Rituximab) at a dosage encompassed by that recited in the claims (see column 8, first paragraph wherein the dosage of 375 mg/m<sup>2</sup> is equal to approximately 750 mg for the hypothetical 75 kg person).

9. Claims 1-7 are rejected under 35 U.S.C. 102(e) or (a) as being anticipated by Goldenberg (US Patent 6183744).

Goldenberg teaches use of antiCD22 antibody or anti CD22 and antiCD20 antibody (which both have the specificity recited in claim 1) plus gamma interferon to treat non-Hodgkins lymphoma (see claims 1-23, especially claims 14 and 15, column 13, second paragraph and columns 15-16). Goldenberg teaches that the antibody can be murine monoclonal or a humanized antibody (see claim 4). Goldenberg teaches use of antiCD20/interferon gamma conjugates or antiCD22/interferon gamma conjugates to treat non-Hodgkins lymphoma (see claim 19). Goldenberg teaches use of a dosage of antibody encompassed by that recited in claim 6 (see column 14). Goldenberg teaches use of commercially available gamma interferon (ACTIMMUNE) wherein said preparation is a human gamma interferon (see column 16).

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.


11. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo-Lopez (US Patent 6,455,043) in view of Eichborn et al. (US Patent 5,145,677).

Grillo-Lopez teaches the treatment of Non-Hodgkin's lymphoma with chimeric or humanized monoclonal antibody against CD20 and IFN- $\gamma$  (see abstract, column 3, second and third paragraph, column 4, first paragraph, column 15, last paragraph continued on column 16 and column 2, last paragraph). Grillo-Lopez teaches use of anti CD20 antibody (Rituximab) at a dosage encompassed by that recited in the claims (see column 8, first paragraph wherein the dosage of 375 mg/m<sup>2</sup> is equal to approximately 750 mg for the hypothetical 75 kg person). Grillo-Lopez does not teach the method of claims 7-9. Eichborn et al. discloses use of human IFN- $\gamma$  for the treatment of lymphoma at a dosage encompassed by that recited in claim 8 (see claim 1 and column 4, last paragraph, wherein the average human is about 2 m<sup>2</sup>). Grillo-Lopez teaches the antibody can be administered after therapeutic agent is given (see column 3, paragraphs two and three). A routineer would have determined the time between IFN- $\gamma$  administration and antibody administration via routine experimentation. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Grillo-Lopez teaches the treatment of Non-Hodgkin's lymphoma with chimeric or humanized monoclonal antibody against CD20 and IFN- $\gamma$  whilst Eichborn et al. discloses use of human IFN- $\gamma$  for the treatment of lymphoma at a dosage encompassed by that recited in claim 8, and Grillo-Lopez teaches the antibody can be administered after therapeutic agent is given wherein a routineer would have determined the time between IFN- $\gamma$  administration and antibody administration via routine experimentation. One of ordinary skill in the art would have been motivated to do the aforementioned because Grillo-Lopez teaches the treatment of Non-Hodgkin's lymphoma with chimeric or humanized monoclonal antibody against CD20 and IFN- $\gamma$  whilst Eichborn et al. discloses use of human IFN- $\gamma$  for the treatment of lymphoma at a dosage encompassed by that recited in claim 8.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.  
Primary Examiner  
Art Unit 1644

  
RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1600 1600